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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/511,822	03/23/2005	Aurelio Orjales Venero	P/4043-153	6533 ·	
2352 OSTROLENK	7590 12/20/2007 FABER GERB & SOFFEN	EXAMINER			
1180 AVENUE OF THE AMERICAS			CHANG, CELIA C		
NEW YORK,	NY 100368403	ART UNIT	PAPER NUMBER		
			1625		
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			12/20/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

			Application No.		Applicant(s)				
		10/511,822		ORJALES VENERO ET AL.					
	Office Action Summary	· }	Examiner		Art Unit				
			Celia Chang		1625				
	The MAILING DATE of this commun	ication appe	ears on the cover shee	et with the c	orrespondence ac	ddress			
Period for Reply									
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).									
Status									
1)⊠	1) Responsive to communication(s) filed on <u>02 October 2006</u> .								
•	•								
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is								
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.								
Disposition of Claims									
4) Claim(s) 1-24 is/are pending in the application.									
4a) Of the above claim(s) is/are withdrawn from consideration.									
5) Claim(s) is/are allowed.									
6)⊠	6)⊠ Claim(s) <u>1-24</u> is/are rejected.								
•	Claim(s) is/are objected to.								
8)[8) Claim(s) are subject to restriction and/or election requirement.								
Applicat	ion Papers								
9) The specification is objected to by the Examiner.									
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.									
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).									
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).									
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
•	under 35 U.S.C. § 119								
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).									
a) All b) Some * c) None of:									
 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 									
Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage									
application from the International Bureau (PCT Rule 17.2(a)).									
* See the attached detailed Office action for a list of the certified copies not received.									
Attachmer	nt(s)								
	ce of References Cited (PTO-892)			view Summary					
3) Infor	ce of Draftsperson's Patent Drawing Review (I mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date				ate Patent Application				

generates a combined print job described in a page description language based on the data of the plurality of print jobs stored in the spool means in the intermediate-code format and the edited print setting information. Further, the display control means controls to restrict print setting items which cannot be edited as part of the combined job and to display the other print setting items as available print setting items which can be edited as part of the combined job and to display the other print setting items as available print setting items which can be edited as part of the combined job and to display the other print setting items as available print setting items which can be edited as part of the combined job and to display the other print setting items as available print setting items which can be edited as part of the combined job and to display the other print setting items as available print setting items which can be edited as part of the combined job and to display the other print setting items as available print setting items which can be edited as part of the combined job and to display the other print setting items as available print setting items which can be edited as part of the combined job and to display the other print setting items as available print setting items which can be edited as part of the combined job and to display the

The term "polymorph 1" in claims 1-18 are ambiguous and indefinite. Please note that the term "polymorph" is referring to multiple crystalline forms. It is unclear are the claims being drawn to bilastin crystalline form I or are the claims being drawn to *polymorphic forms of form I* which means not form 1. If the claims are drawn to a single crystalline form 1, then, the term polymorph should be deleted.

The term "at least one of isopropylic alcohol and n-butanol" in claims 19-24 is confusing and may be broadening of the base claim. Please note, at least one includes other solvent which is not encompassed by the base claim. In addition, "at least one....and..." is confusing, is it propanol <u>or</u> butanol? or at least one mixture? or a mixture containing one of the alcohol? Clarification is required.

The term "preparing a medicinal product for treating allergic reactions and pathological processes mediated by histamine" is very confusing. Is this a process of making a medicinal composition? Please note that there is no steps in the claims since "incorporating" is not a step and criticality of how such process is conducted must be explicitly stated. Further, it is unclear what was made? A therapeutically effective amount? An antihistamic effective amount? Please note that a process "mediated by...." includes both too much and too little. An antihistamic compound can only treating too much histamine. In addition, for a pharmaceutical composition, the active ingredients are normally mixed with pharmaceutically acceptable carriers, which constitutes a composition. Clarification is required.

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3. Claims 1-3, 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A product cannot be separated from *all* its physical properties. Applicants have not demonstrated that a product with X-ray analysis <u>alone</u> without the IR spectrum nor vice versa.

4. Claims 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to "procedure" consisting of one step, i.e. heating in a solvent.

Please note that a procedure must contain steps of how the process is being operated. Absent of starting material, conditions such as temperature, concentration, for how long, and separation, the claims are inoperable. Heating alone does not obtain the claimed product.

5. Claims 4-5, 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with - which it is most nearly connected, to make and/or use the invention.

"The standard for determining whether the specification meets the enablement requirement [in accordance with the statute] was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.*, 857 F.2d 778,

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785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

In the instant case, the rejected claims 4-5, 15-18 which were not described in the specification. Based on the level of skill as stated in the state of the art reference *Kirk-Othmer Encyclopedia of Chemical Technology* Copyright © 2002 by John Wiley & Sons, Inc., pp. 95-147, Article Online Posting Date: August 16, 2002, the amount of guidance in the specification, the disclosure does not contain sufficient information to enable one skilled in the pertinent art for recovery of such a product as claimed.

Specifically, the amount of guidance or direction needed to enable an invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. In the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof."

In the instant case, the state of the art of polymorph recovery is highly unpredictable. See for example *Kirk-Othmer Encyclopedia of Chemical Technology* Copyright © 2002 by John Wiley & Sons, Inc., pp. 95-147, Article Online Posting Date: August 16, 2002. This article

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indicates that many uncertain factors determine morphology, and specifically that the appearance of the crystalline product and its processing characteristics (such as washing and filtration) are affected by crystal habit (i.e., the general shape of a crystal). Relative growth rates of the faces of a crystal determine its shape. Faster growing faces become smaller than slower growing faces and, in the extreme case, may disappear from the crystal altogether. Growth rates depend on the presence of impurities, rates of cooling, temperature, solvent, mixing, and supersaturation. Furthermore, the importance of each of these factors may vary from one crystal face to another, see page 114.

The reference also teaches that polymorphism is a condition wherein crystalline form is intimately associated with processing ("Polymorphism is a condition in which chemically identical substances may crystallize into different forms. Each form is, however, only stable (thermodynamically) in a certain range of temperature and pressure. In the case of ambient pressure, eg, ammonium nitrate exhibits four changes in form between -18 and 125°C:

$$\begin{array}{c} 169,6^{\circ}C \\ \text{liquid} \longleftrightarrow \text{cubic} \longleftrightarrow \text{trigonal} \longleftrightarrow \text{orthorhombic} \ I \longleftrightarrow \text{orthorh$$

Transitions from one polymorphic form to another may be accompanied by changes in process conditions (temperature, pressure, shear or solution composition), transitions from one polymorphic form to another and lead to formation of a solid product with unacceptable properties (eg, melting point or dissolution rate).

Critical elements such as temperature, time, concentration, kind and ratio of mixture of solvents etc. must be explicitly limited for any procedure to produce the particular crystal as claimed. Especially, it is unclear whether the claims are making form 1 bilastin or "polymorph" of bilastin form 1.

6. Claims 9-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270